UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,370	07/01/2003	Paul E. Young	PF383D1	4500

22195 7590 07/28/2005

HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,370	YOUNG ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-44* is/are pending in the application.

4a) Of the above claim(s) *37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-36 and 38-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

500

Detailed Action

The Election filed on 7/8/05 in response to the Office Action of 6/21/05 is acknowledged and has been entered. Applicant elected group III drawn to antibodies that specifically bind polypeptides comprising amino acid sequences of SEQ ID NO:2, represented by new claims 22-42, with traverse.

Newly submitted claim 37 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 37 is directed to a method of detecting a protein comprising contacting the biological sample with an antibody or fragment thereof. These inventions are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used for affinity chromatography. Hence, this claim would have been restricted had it been originally presented.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 37 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The traversal is on the ground(s) that restriction remains improper unless the examiner can show that the search an examination of groups I-IV would entail a "serious burden" (MPEP 803). Applicant argues that since searches for proteins, nucleic acids encoding such proteins, and antibodies that specifically bind such proteins commonly overlap, the combined search and examination of such compositions would not entail a serious search burden. This is not found persuasive. Different searches and issues are involved in the examination of each group. As outlined in the Office Action, these groups represent products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. Currently, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of all such peptides in the databases would require extensive searching and review and would invoke a high burden of search. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. A search of the nucleic acid molecules of

group I would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group II. As such, it would be burdensome to search the inventions of groups I and II. Furthermore, searching the inventions of group II and group III would impose a serious search burden. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibody of group III. Furthermore, antibody which binds to an epitope of a polypeptide of group II may be known even if a polypeptide of group II is novel. In addition, the technical literature search for the polypeptide of group II and the antibody of group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target. Furthermore, searching the inventions of group I and group III would impose a serious search burden since a search of the polynucleotides of group I would not be used to determine the patentability of any antibody of group III, and vice-versa. Therefore, examination of groups I-IV would result in a "serious burden" for the examiner.

For these reasons the restriction requirement is deemed proper and is therefore made FINAL.

Claims 1-21 have been cancelled.

Claims 22-44 are new.

Claim 37 has been withdrawn under CFR 1.142(b) as being drawn to a non-elected invention.

Claims 22-36 and 38-44 are currently under consideration.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 22-44 of this application.

Applicant is not entitled to the priority date of the provisional application 60/049942 (June 17, 1997); however, Applicant is entitled to the priority date of application 09/097681 (**June 16, 1998**). The pending claims of the instant application are drawn to SEQ ID NO:2, a sequence which is absent in provisional application 60/049942. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW MATTER** rejection.

Claims 29 and 41 recite "wherein said antibody or fragment thereof is human". Descriptions of human antibodies are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 22-36 and 38-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Godowski et al. (US Patent 6,121,415, September 19, 2000). Godowski et al. teach a sequence (amino acids 256-395 of Human NRG3B2 / SEQ ID NO:23) with a local similarity of 92.3% to amino acids 1-141 of SEQ ID NO:2 of the instant application. Because of the high degree of homology, antibodies or antibody fragments capable of binding regions within amino acids 256-395 of Human NRG3B2 would also bind regions within amino acids 1-141 SEQ ID NO:2. Godowski et al. teach monoclonal antibodies, polyclonal antibodies, chimeric antibodies, Fab fragments, and antibody

fragments capable of binding SEQ ID NO:23 (Human NRG3B2) (see column 39 and 40 in view of the definition of "antibody" and "monoclonal antibody" in column 17 and 18, in particular). They further teach labeled antibodies (column 40, in particular). They further teach the antibodies can be used in any known assay method, such as direct and indirect sandwich assays (column 40, in particular). As evidenced by Coligan et al. (Current Protocols in Immunology, 1991, John Wiley & Sons, USA, pages 2.1.2-2.1.22), direct and indirect sandwich assays are ELISAs (see page 2.1.2 and 2.1.3, in particular). They further teach hybridoma cells capable of producing the antibodies (column 40, in particular). They further teach human and humanized forms of the antibody (column 41, in particular). They further teach that SEQ ID NO:23 (Human NRG3B2) can include glycosylated and unglycosylated variants (column 32), thus it is inherent that the taught antibodies are capable of binding the glycosylated and unglycosylated variants.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600